K111644

Greatbatch Medical

OCT - 3 2011

510(k) Summary

Applicant Information

Submitter's Name/Address:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441
Contact Person:	Kristi Fox Regulatory Affairs Specialist Tel: 763-951-8205 Fax: 763-559-0148 kfox@greatbatchmedical.com
Date Prepared:	June 10, 2011

Device Information

Trade Name:	MobiCath™ Transseptal Needle
Common Name:	Transseptal Needle
Classification Name:	Trocar
Product Code:	DRC
Regulation:	Class II 21 CFR 870.1390
Classification Panel:	Cardiovascular
Predicate Devices:	St. Jude Medical BRK™ Transseptal Needle (*K072278*) Thomas Medical Transseptal Needle (*K011727*)

Device Description

The MobiCath Transseptal Needle consists of a thin-walled stainless steel cannula which is curved in the distal section to facilitate positioning in the cardiac anatomy when used in conjunction with a transseptal catheter or introducer. The proximal end of the needle is bonded to an ergonomic handle with an integrated pointer to show the orientation of the curve section and a two-way stopcock to facilitate air aspiration, fluid infusion, blood sampling, and pressure monitoring. The Transseptal Needle includes a stylet with an over-molded hub designed to attach to the proximal end of the needle assembly.

Indications for Use

The MobiCath™ Transseptal Needle is used to create the primary puncture in the inter-atrial septum to facilitate the passing of an introducer or catheter through the septum from the right side of the heart to the left side.

Predicate Device Comparison / Technological Characteristics

The MobiCath™ Transseptal Needle has similar indications for use, technological characteristics and principles of operations as the market cleared St. Jude Medical BRK™ Transseptal Needle (*K072278*) and Thomas Medical Transseptal Needle (*K011727*). The MobiCath Transseptal Needle and BRK Transseptal Needle differ in tip bevel and cannula design. The MobiCath Transseptal Needle shares similar design features as the Thomas Medical Transseptal Needle but is available in more lengths and curve sizes.

Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended and does not raise new questions of safety or efficacy compared to the predicate devices.

Summary of Testing

The MobiCath™ Transseptal Needle passed all verification specification criteria for dimensional, functional, packaging, sterilization, biocompatibility and shelf life tests. Test results confirm the device performs as intended without raising additional questions of safety and efficacy when compared to the predicates. Given the similar technological characteristics and principles of operation of the MobiCath™ Transseptal Needle and the predicate devices, it was determined that pre-clinical (animal) or clinical study was not necessary. The following non-clinical tests were performed for the MobiCath Transseptal Needle:

- Sterilization Testing per ISO 11135-1
- Shelf Life
- Biocompatibility per ISO 10993-1
    - Cytotoxicity
    - Sensitization
    - ISO Irritation/Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Material Mediated Rabbit Pyrogen
    - Hemocompatibility
    - Hemolysis Test
    - Partial Thromboplastin Time
    - Platelet and Leukocyte Counts
    - Complement Activation – C3a and SC 5b-9
    - Thrombosis
- Performance – Bench:
    - Visual
    - Dimensional
    - Functional
        - Tensile strength
        - Torque
        - Resistance to breakage
        - Stopcock separation force
        - Hub to stopcock retention force
        - Stopcock gauging
        - Leakage
        - Stopcock ease of assembly
        - Stopcock stress cracking

- Needle and stylet insertion through dilator

Statement of Equivalence

The MobiCath™ Transseptal Needle has similar indications for use, principles of operation, and technological characteristics as the identified predicates. Based on these similarities, in addition to the results from safety and performance testing, the MobiCath™ Transseptal Needle is considered substantially equivalent to the St. Jude Medical BRK™ Transseptal Needle (*K072278*) and Thomas Medical Transseptal Needle (*K011727*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-0609
Silver Spring, MD 20993-0002

Greatbatch Medical
c/o Ms. Kristi Fox
Regulatory Affairs Specialist
2300 Berkshire Lane North
Minneapolis, MN 55441

OCT - 3 2011

Re: K111644
Trade Name: MobiCath ™ Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: II (two)
Product Code: DRC
Dated: September 22, 2011
Received: September 26, 2011

Dear Ms. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use Statement

510(k) Number (if known): K111644

Device Name: MobiCath Transseptal Needle

Indications for Use:

The MobiCath™ Transseptal Needle is used to create the primary puncture in the inter-atrial septum to facilitate the passing of an introducer or catheter through the septum from the right side of the heart to the left side.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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